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TITLE: Integrated Clinical Information System Collaboration Project (CPOE)

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14. ABSTRACT

Objective: Identify adverse events as they relate to the identification of harm or injury to the patient due to medication administration. Hypothesis: CPOE with decision support decreases the probability of adverse events caused by medication administration. The IHI's trigger tool process consists of a retrospective patient chart review completed by a team of nursing staff receiving training and direction from a staff physician. Charts are reviewed using a structured approach to identify significant medication events with harm. Based on the large size, 7,500 each population, of the comparison samples, a convenience sampling methodology should be sufficient to insure randomness. Samples were pulled based on admission or discharge dates from a representative time period for both before and after CPOE implementation. In order to eliminate any seasonal bias, the time periods should be consistent for both samples. With an approximate 3,300 admissions per month, a timed based convenience sample should minimize any other bias as the "population" for that time period will become the sample. Other qualifiers may be included in both samples to exclude certain patient populations from the study.

15. SUBJECT TERMS
ADE's (adverse drug events), trigger tool, harm

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I. INTRODUCTION:

Phase II of the Integrated "Clinical Information System Collaboration Project: IHI Trigger Tool" has been completed. The contract term ended February 28, 2011. The proposal for this study included work in progress from Phase I. Data collection for phase I has been completed along with a comparison and analysis of data pre and post-CPOE.

Objective: Identify adverse events as they relate to the identification of harm or injury to the patient due to medication administration.

Hypothesis: CPOE with decision support decreases the probability of adverse events caused by medication administration.

This project is Phase II in the "Integrated Clinical Information System Collaboration Project." Phase I of the project included a surrogate measurement for adverse medication outcomes through the collection of data on the number of major contraindicated medication alerts. A high level alert indicates possible serious drug-drug interactions that will likely result in patient harm. Pre-CPOE only the pharmacist saw these alerts. Post-CPOE the physicians saw these alerts initially and were expected to act on them. If the physicians did not take action, the alerts would then be seen by the pharmacist. In the Post-CPOE environment, this dual monitoring system, by physician and pharmacist, is seen as a potential way of reducing potential harmful ADE's. Although Mission Hospital assessed mortality rates along with ADEs in Phase I, there was no provision for effectively measuring ADEs in relation to mortality rates. For phase II of this study Mission Hospital used a tool developed by The Institute for Health Care Improvement (IHI). This is a Trigger Tool for identifying ADEs with harm. This tool includes a list of known ADE triggers and instructions for collecting the data needed to assess the number of ADEs per 1,000 doses and the percentage of admissions with ADEs. Mission Hospital obtained permission from the Institute for Health Care Improvement (IHI) to use this tool to assess and compare patient harm due to medication errors pre and post CPOE.

II. BODY:

The Institute for Healthcare Improvement's (IHI) trigger tool process consisted of a retrospective patient chart review completed by a team of nursing staff receiving training and direction from a staff physician. Charts were reviewed using a structured approach to identify significant medication events with harm. Based on the large size of the comparison samples, a convenience sampling methodology was used to insure randomness. Samples were pulled based on discharge dates from a representative time period both before and after CPOE implementation. In order to eliminate any

seasonal bias, the time periods were consistent for both samples. With approximately 3,300 admissions per month, a timed based convenience sample should minimize any other bias as the "population" for that time period will become the sample.

Statistical Analysis:

A statistical sample was calculated using Minitab 14 statistical software. A two proportion sample size calculation was used to determine the appropriate sample size for comparison before and after CPOE implementation. An assumed pre-CPOE defect rate of 8% was used for the hypothesized defect rate, with a post-CPOE rate of 6%, indicating the ability of the sample size to detect a change of 2%. The samples were calculated using an alpha (significance) level of .05 and a statistical power of 0.9. The resulting sample size based on the preceding criteria would be 3,419 for EACH population. For this study 3,450 patient charts were reviewed for each of two sample periods.

Study Design:

This tool counted only ADEs with harm to the patient from medications whether or not they resulted in an identifiable error. Harm was defined as "temporary or permanent impairment of physical or psychological body function or structure." Based upon the IHI error classification scheme, the tool excluded the following categories and described medication errors that do not cause harm:

Category A: Circumstances or events having the capability to cause error
Category B: An error not reaching the patient
Category C: An error reaching the patient but not causing harm
Category D: An error reaching the patient and requiring monitoring or intervention to confirm resulting in no harm to the patient

The tool included categories E, F, G, H, and I and described medication errors that do cause harm.

Category E: Temporary harm to the patient and requiring intervention
Category F: Temporary harm to the patient and requiring initial or prolonged hospitalization
Category G: Permanent patient harm
Category H: Intervention requiring sustaining life
Category I: Patient death

The IHI provides a list of triggers to be useful in identifying ADEs. A review of patient charts was conducted and a team of registered nurses along with the PI worked together to agree on the IHI list of triggers and added a few other triggers they deemed appropriate for the study (appendix A).

Once the team decided on this list of triggers the next step was to review a sample of patient records. Each patient record review resulted in the generation of a form-based report, whether or not the record turned out to contain triggers and ADEs (appendix B). The team reviewed randomly selected patient charts from those patients admitted for greater than two days. Historical data was collected and analyzed to compare pre- and post-CPOE implementation. At the completion of 25 reviewed charts, a summary sheet was completed (appendix C).

Results:

The following measures were calculated based upon aggregated ADE assessment data:

- Total ADEs per 1,000 Doses (table 1)
    - The total number of ADEs per 1,000 doses was calculated as the total number of ADE's identified in a sample of inpatient records, divided by the total number of medication doses administered to those patients. The result is then multiplied by 1,000.

Pre- Vs. Post-CPOE ADE's per 1,000 doses			
	Total ADE's	Total Medication Doses	% per 1,000 Doses
Pre-CPOE	302	646,948	.46 events/1,000 doses
Post-CPOE	257	669,449	.38 events / 1,000 doses

(Table 1)

P value = 0.021

- The percent of Inpatient admissions associated with any ADE (table 2)
    - The total number of ADE's was calculated as the number of inpatient admissions associated with an ADE, divided by the total number of admission

encounters for the selected time period, multiplied by 100 and expressed as a percentage.

Percent of Inpatient Admissions with an ADE 3,450 Consecutive patients per year				
Pre-CPOE / 2007		Post-CPOE / 2008		
Total Admissions	% of Admissions	Total Admissions	% of Admissions	2007-2008 Change
273	7.91%	235	6.81%	-1.1%

(Table2)

P value = 0.080

- Total ADEs per inpatient admission (table 3)
  - The total number of ADEs per inpatient admission was calculated as the number of total ADE's, all harm categories, divided by the total number of admission encounters for a selected time period, multiplied by 100 and expressed as a percentage.

Percent of Patient Admissions with an ADE 3,450 Consecutive patients per year				
Pre-CPOE / 2007		Post-CPOE / 2008		
Total Admissions	% of Admissions	Total Admissions	% of Admissions	2007-2008 Change
302	8.75%	257	7.45%	-1.3%

(Table 3)

P value = 0.047

- Total Category E ADEs per inpatient admission (table 4)
  - The total number of Category E ADEs was calculated as the number of inpatient admissions associated with a category E ADE, temporary harm requiring intervention, divided by the total number of admission encounters for a selected time period, multiplied by 100 and expressed as a percentage.

Pre-CPOE / Total Consecutive Patients each Period = 3,450				
	Category	No. of ADE's	% of Total Patients	2007-2008 Change
Pre-CPOE	E	254	7.36%	
Post-CPOE	E	211	6.12%	-1.23%

(Table 4)

P value = 0.039

- Inpatient admission associated with a category E ADE per encounter (table 5)
  - The total number of individual patients who were identified as having category E harm per inpatient admission was calculated as the number of category E ADEs, temporary harms requiring intervention, divided by the total number of admission encounters for a selected time period, multiplied by 100 and expressed as a percentage.

Pre-CPOE / Total Consecutive Patients each Period = 3,450				
	Category	No. of ADE's	% of Total Patients	2007-2008 Change
Pre-CPOE	E	226	6.55%	
Post-CPOE	E	189	5.48%	-1.07%

(Table 5)

P value = 0.061

- Total Category G ADEs per inpatient admission (table 6)
  - The total number of Category G ADEs was calculated as the number of inpatient admissions associated with a category G ADE, those causing permanent patient harm, divided by the total number of admission encounters for a selected time period, multiplied by 100 and expressed as a percentage.

Pre-CPOE / Total Consecutive Patients each Period = 3,450				
	Category	No. of ADE's	% of Total Patients	2007-2008 Change
Pre-CPOE	G	1	0.03%	
Post-CPOE	G	2	0.06%	0.03%

(Table 6)

P value = 0.564

- Total Category H ADEs per inpatient admission (table 7)

  The total number of Category H ADEs was calculated as the number of inpatient admissions associated with a category G ADE, those requiring intervention to sustain life, divided by the total number of admission encounters for a selected time period, multiplied by 100 and expressed as a percentage.

Pre-CPOE / Total Consecutive Patients each Period = 3,450				
	Category	No. of ADE's	% of Total ADEs	2007-2008 Change
Pre-CPOE	G	7	0.20%	
Post-CPOE	G	5	0.14%	-0.06%

(Table 7)

P Value = 0.563

In summary, total ADE's with harm were assessed Pre- vs. Post-CPOE. Incidents by severity are shown in tables one and two. Overall there were 302 total ADEs that occurred in 273 patients' pre-CPOE and a total of 257 total ADEs that occurred in 235 patients' post-CPOE (tables 8 and 9).

Total Number of ADEs					
Total Consecutive Patients = 3,450					
	Pre-CPOE		Post-CPOE		
Category	Total No. of ADE's	% of Total ADEs / Patient Admission	Total No. of ADE's	% of Total ADEs / Patient Admission	2007-2008 Change
E	254	7.36%	211	6.12%	(1.2%)
F	37	1.07%	36	1.04%	(0.0%)
G	1	0.03%	2	0.06%	0.0%
H	7	0.20%	5	0.14%	(0.1%)
I	3	0.09%	3	0.09%	0.0%
Total	**302**	**8.75%**	**257**	**7.45%**	**(1.3%)**

(Table8)

Total Number of Inpatient Admissions Associated with an ADE					
Total Consecutive Patients = 3,450					
	Pre-CPOE		Post-CPOE		
Category	Total No. of ADE's	% of Total ADEs / Patient Admission	Total No. of ADE's	% of Total ADEs / Patient Admission	2007-2008 Change
E	226	6.55%	189	5.48%	(1.1%)
F	36	1.04%	36	1.04%	0.0%
G	1	0.03%	2	0.06%	0.0%
H	7	0.20%	5	0.14%	(0.1%)
I	3	0.09%	3	0.09%	0.0%
Total	**273**	**7.91%**	**235**	**6.81%**	**(1.1%)**

(Table 9)

Individual reviewers classified events by patient preventable harm to determine severity by incident. The number of ADEs assessed per 1,000 doses or number of ADEs per admission yielded a statistically significant difference indicating fewer ADEs post versus pre CPOE. Only when the percent of admissions was analyzed for the occurrence of any ADE did our results fall short of statistical significance.

The distribution of severity of ADEs weighted heavily toward harms considered to be temporary. Categories E and F made up 8.43% of the patient population pre-CPOE and 7.1% post-CPOE.

The occurrence of temporary harm in subcategory E showed a lower incidence post CPOE that reached statistical significance. Category F harm remained relatively unchanged pre- versus post-CPOE. G-I Harm, considered to be permanent or life-threatening, were not found to reflect statistically significant differences between the two groups. The incidence of most serious harm, category F-I, was far less common, such that no discernable difference could be assessed pre- vs. post CPOE. There were an equal number of category I deaths related to medication administration during the course of the study, three pre-CPOE and three post-CPOE.

Although the differences in ADEs pre- versus post- CPOE are relatively small, the large number of records reviewed in this study indicates that CPOE, even early in the course following its deployment, results in a lower incidence of ADEs. These changes were evident within the first year of CPOE when physician experience using the system was still recent and when there had been little deployment of supporting rules or decision support. These results showing early positive results suggest that the addition of increasingly sophisticated decision support may be expected to yield greater benefit over time. In this context, CPOE should be viewed as a critical piece of the EHR foundation that may be expected to result in a continuing improvement in medication safety.

III. KEY RESEARCH ACCOMPLISHMENTS:

- Assessment of the impact of CPOE on ADEs in a large patient population
- Analysis of ADEs by severity subcategory and by both admission occurrences and per 1,000 doses.

IV. REPORTABLE OUTCOMES:

There are no manuscripts, abstracts, presentations; patents and licenses applied for and/or issued; degrees obtained that are supported by this award; development of cell lines, tissue or serum repositories; informatics such as databases and animal models, etc.; funding applied for based on work supported by this award; employment or

research opportunities applied for and/or received based on experience/training supported by this award at this time.

V. CONCLUSION:

In this study, we evaluated the rates and type of ADEs pre- vs. post-CPOE and found that the overall rates were fairly similar. It was determined that Mission Hospital had comparable incident rates of ADE's as compared to previous studies[1].

Evaluation of medication harms suggests that the majority of harm can be eliminated by use of decision support tools and protocols. This study did not show significant reductions in drug harm with the use of CPOE. Further studies should be done to include harms to determine impact on length of stay and cost per case. In addition, these harms were not assessed by provider type. In some cases the preventable harm could be attributed to direct patient care of nursing staff. These studies could increase awareness of nursing issues concerning patient medication administration and monitoring post medication delivery.

VI. APPENDICES:


Appendix_A.docx


Appendix_B.docx


Appendix_C.docx

VII. QUARTERLY AND YEAR TO DATE EXPENDITURES:

Reporting period from 10/01/2010 to 02/28/2011

PI: James Keel, MD 5. Telephone No. (828) 213-3506

Institution: Mission Hospitals

Project Title: "Integrated Clinical Information System Collaboration Project (CPOE) – Phase 2"

Current staff, with percent effort of each on project:

James Keel, MD, PI 50 % Research Nurses 80 %

Karen Roby, Project Manager 80 %

Expenditures to date (as applicable):